

PATENT
09/849,022
Docket 091/005

REMARKS

This paper is responsive to the Office Action dated June 10, 2004 which is the third action on the merits of the application. The action has been made final.

Claims 1-3, 6, 8-9, 13, and 15-36 are pending in the application and stand variously rejected. By way of this amendment, certain claims have been changed. The amendments are supported by the claims as previously presented, and throughout the specification. No claim has been added or cancelled since the last Office Action.

Further consideration and allowance of the application is respectfully requested.

Interview Summary:

The undersigned wishes to express his gratitude to Examiner Thái-An N. Ton, Examiner Deborah Crouch, and Examiner Joseph Weitach for the helpful interview regarding this application held at the Patent Office on September 2, 2004. Possible amendments to the claims were discussed. This paper incorporates amendments and remarks presented during the interview.

Double Patenting

The double patenting rejection over USSN 10/039,956 has been withdrawn, for which applicant is grateful.

Applicant acknowledges the provisional non-statutory double patenting rejection over copending application no. 09/530,346. Applicant again undertakes to file a terminal disclaimer with respect to the '346 application, or otherwise address this issue, upon indication that the present application is otherwise in condition for allowance.

Rejections under 35 USC § 112 ¶ 1:

The pending claims stand rejected under the enablement requirement of § 112 ¶ 1. The Office Action indicates that the specification is enabling for methods of obtaining or producing genetically altered hES cells in the absence of feeder cells on the extracellular matrix. However, the Office Action challenges the scope of the claims because the claims do not explicitly require a feeder cell conditioned medium be used in the cell culture.

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Applicant respectfully disagrees.

First of all, it is important to separate product claims from claims covering a process for obtaining a product. Claims 8, 9, 13, 15, and 25-36 are product claims: namely, a cell population. The cells have been transfected to express a heterologous gene, but there is no limitation to a particular environment, condition, or time.

It is well established in the law that the specification need not teach all possible ways of making a claimed product, as long as at least one method of making the product is provided:

The enablement requirement is met if the description enables any mode of making and using the claimed invention.

— *Engel Industries, Inc. v. Lockformer Co.*, 20 USPQ2d 1300 (Fed. Cir. 1991).

For example, patents to chemical structures are covered according to the structure, and are not limited to the method by which they were synthesized in the working examples. By analogy, the cell populations of claims 8, 9, 13, 15, and 25-36 are enabled by the specification, not limited by the method by which they were prepared in the working examples.

Indeed, the U.S. Patent & Trademark Office has always taken the position that process limitations in a product claim do not distinguish the product from the same product made by a different method.

Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. — MPEP § 2113.

Since only the cell population is covered in claims 8, 9, 13, 15, and 25-36, and not the surrounding environment, the method by which they were previously cultured is not relevant.

Thus, product claims 8, 9, 13, 15, and 25-36 are enabled because the specification describes and illustrates an effective method by which the claimed cell population can be produced. Claims 16, 18, and 19 are methods for *using* the product of claim 9, not methods for making it. These claims are enabled because the starting product is enabled, and the specification provides a variety of methods of differentiation.

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Claims 1-3, 6, 17, and 20-24 cover methods for making genetically altered cells. For these claims, applicant has adopted Examiner Woitach's suggestion to indicate that the cells are "maintained" during genetic alteration. This helps the reader understand that the cells do not necessarily have to be proliferating during the process. Many of the vectors listed in the specification can be used for doing genetic alteration of non-proliferating cells.

Furthermore, these claims do not require that the cells be maintained in an undifferentiated state. In fact, step c) of independent claims 1 and 17 both explicitly require that the cells become differentiated. Surely the Examiner will agree that culture ingredients useful for proliferating undifferentiated hES cells (such as conditioned medium) will not be needed in a process where the cells are allowed to differentiate.

Thus, both the product and the method claims now pending in this application meet the enablement requirements of § 112 ¶ 1. Withdrawal of this rejection is respectfully requested.

Request for a further Interview

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

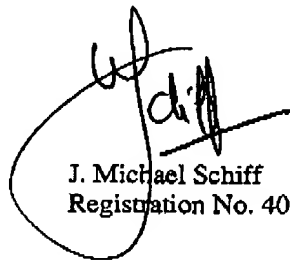
In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests an interview by telephone.

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Fees Due

No fee is due for entry and consideration of this Amendment. Nevertheless, should the Patent Office determine that an extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. Michael Schiff", is written over a circular stamp. The stamp contains the text "J. Michael Schiff" and "Registration No. 40,253".

J. Michael Schiff
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